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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,411	01/30/2006	Fabio Rinaldi	27419310	5530

26774 7590 12/05/2008

NIXON PEABODY LLP - PATENT GROUP
1100 CLINTON SQUARE
ROCHESTER, NY 14604

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
12/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,411	RINALDI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 5-8 were amended and claims 9-12 were newly added in a preliminary amendment filed 30 January 2006. As a result, claims 1-12 are examined herein on the merits for patentability. No claim is allowed at this time.

Specification

The amendment to the specification filed 30 January 2006 detailing the national stage entry information has been entered.

It is noted that the claims as originally filed contain subject manner that does not find support in the specification. In particular, claim 6 as originally filed, and claims 6 and 10 as filed in the preliminary amendment, contain amounts for the components of the composition that do not find support in the specification, such as the range for spermidine trihydrochloride of 0.25-0.5 mg. Applicants are required to amend the specification to provide adequate support for these values in such a manner as to not enter new matter into the specification.

Information Disclosure Statement

The information disclosure statement filed 30 January 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document;

each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the Foreign Patent Documents referred to therein have been crossed out.

Claims and Specification Objections

1. Claims 6 and 10 are objected to because of the following informalities: Calcium d-Pantothenate, which is vitamin B5, is misspelled as Calcium d-Panthotenate. Appropriate correction is required.

2. The disclosure is objected to because of the following informalities: Calcium d-Pantothenate, which is vitamin B5, is misspelled as Calcium d-Panthotenate in Examples 1 and 2, pg. 4, ln. 25 and pg. 5, ln. 10. Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 112

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 provide for the use of spermine and/or spermidine, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). As a result, claims 1 and 2 are not further considered on the merits.

Claims 8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 8 and 12, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 3, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Raisfeld (US 4,507,321).

Raisfeld discloses topical or oral compositions comprising a polyamine, such as spermine or spermidine, which are useful to regulate, i.e., stimulate or inhibit, epithelial cell growth (Abstract; col. 2, ln. 68; col. 3, ln. 1, 27-33 and 58-68; and col. 3, ln. 1-19). Raisfeld further discloses examples wherein topical or oral formulations comprise spermine or spermidine (Examples 1, 2 and 4-11). See also claims 1, 2, 5, 8, 9, 13 and 14.

2. Claims 3, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Charonis et al. (WO 94/12464; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Charonis et al. disclose polyamines which are useful for treating tissue aging (Abstract), wherein the composition is suitable for topical or oral administration (pg. 11, ln. 20-22), and the preferred polyamines include spermine and spermidine (claims 1 and 4-8).

3. Claims 3, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ilenchuk et al. (WO 99/51213; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Ilenchuk et al. disclose the topical administration of polyamines in the palliative treatment of chronic diseases and disorders of epithelial tissue (Abstract). Ilenchuk et al. disclose that the use of polyamines for therapeutic treatment of tissue damage is known (pg. 12, ln. 33-35), wherein it is taught that polyamines regulate, stimulate or inhibit epithelial growth (pg. 13, ln. 1-11). Ilenchuk et al. further disclose that the preferred polyamines include spermidine and spermine in the free base form or acid addition salt form (pg. 19, ln. 20, 21; and pg. 20, ln. 15-18), and the compositions are suitable for topical and oral administration (pg. 20, ln. 25-35). Ilenchuk et al. disclose several examples wherein spermine or spermidine is formulated into topical or oral administration formulations (pg. 22-27, Preparations 1-11). See also claims 1-8.

4. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckart et al. (EP 0 884 046 A1; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Eckart et al. disclose cosmetic compositions with photoprotective properties, wherein the compositions comprise Vitamin E, Vitamin C, and at least one natural polyamine (Abstract). Eckart et al. disclose that the compositions are suitable for retention of elasticity and of moisture in the skin (col. 1, ln. 7-12). Eckart et al. further

disclose that especially preferred natural polyamines are spermine and spermidine (col. 2, ln. 13-14); and that the compositions are formulated as cosmetic skin-care products (col. 4, ln. 42-44). Eckart et al. disclose an example wherein a sun protection balm was prepared comprising D-panthenol, Vitamin C, spermine, and tocopherol (Example 2). See also claims 1, 8 and 11.

5. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. (WO 98/06376; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Wolf et al. disclose a nail strengthening composition comprising tocopherol, pantetheine, pyridoxine, biotin and spermine (Example 1; and claims 18-20).

6. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn et al. (WO 96/23490; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Hahn et al. disclose compositions and formulations containing polyamines for inhibiting skin irritation in animals (Abstract). Hahn et al. further disclose that the composition is for topical administration and comprises spermine or spermidine (claims 1 and 2).

7. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsubara et al. (JP 2003/113047 A; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Matsubara et al. disclose a hair cosmetic preferably comprising spermine or spermidine (Abstract).

8. Claims 3, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Minoshima et al. (JP 07/268323 A; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Minoshima et al. disclose a pharmaceutical antioxidant preparation comprising spermine or spermidine, tocopherol and ascorbic acid (Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 5, 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoshima et al. (JP 07/268323 A) in view of Henderson (WO 00/37087) and Ioannides (WO 02/15860; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Applicant's claims

Applicants claim a composition comprising 200 mg MSM, 0.25-0.5 mg spermidine 3HCl, 60-90 mg Vitamin C, 33 mg Vitamin E, 3.7 mg Vitamin B6, 4 mg calcium d-pantothenate, 0.23 mg d-biotin, 7.5 mg zinc as amino acid chelate, 1.25 mg copper as amino acid chelate, 2.25 mg manganese as amino acid chelate, and 0.03 mg selenium as Se yeast.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Minoshima et al. teach a pharmaceutical antioxidant preparation comprising spermine or spermidine, tocopherol (Vitamin E) and ascorbic acid (Vitamin C) (Abstract).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Minoshima et al. do not teach the composition further comprising methyl sulfonyl methane, Vitamin B6, calcium d-pantothenate, biotin, zinc, copper and manganese amino acid chelates, and selenium, as instantly claimed. However, Henderson teaches that amino acid chelates of copper, zinc and manganese, and optionally selenium are

known to reduce free radical cellular oxidative stress by strengthening and maintaining the activities of enzymes known to remove harmful superoxides, peroxides, and hydroxides (pg. 8, ln. 24-27). Henderson teaches that proper metabolic functioning of minerals such as copper, zinc and manganese in addition to or independent of selenium play an important role in maintaining the function of oxidative enzymes that relate to oxidative bursts in neutrophils and macrophages, and in controlling or alleviating free radical cellular oxidative toxicity (pg. 10, ln. 11-20). Henderson further teaches that vitamins are essential for maintaining good health (pg. 11, ln. 19), and vitamins C, E, B6, biotin and pantothenic acid are advantageously added to a comprehensive dietary supplement; wherein Vitamins C and E also provide antioxidant function (pg. 12, ln. 12-32). Henderson teaches that the preferred amount in parts by weight of zinc is 1-25 x 10^{-3}, selenium is 1-75 x 10^{-6}, copper is 0.1-2 x 10^{-3}, manganese is 0.1-10 x 10^{-3}, Vitamin C is 10-500 x 10^{-3}, Vitamin E is 1-500 IU, Vitamin B6 is 0.1-20 x 10^{-3}, biotin is 25-200,000 x 10^{-6}, and pantothenic acid is 1-50 x 10^{-3} (pg. 11, ln. 1-14; and pg. 12, ln. 15-28).

Minoshima et al. do not teach the addition of methylsulfonylmethane to their pharmaceutical compositions. However, Ioannides teaches that methylsulfonylmethane (MSM) is added to ascorbic acid as an anti-inflammatory and to accelerate healing (pg. 25, ln. 13-16).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add vitamins and minerals to the formulations of Minoshima et al. to enhance the anti-oxidative properties and improve overall health, as reasonably taught by Henderson; as well as adding methylsulfonylmethane as an anti-inflammatory agent to accelerate healing, as reasonably taught by Ioannides.

With respect to the amounts of each component listed in instant claims 6 and 10, the examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616